

PTO/PCT Rec'd 26 SEP 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: CHAIN=4A

In re Application of:	)	Art Unit:
	)	
Daniel CHAIN	)	
	)	
IA No.: PCT/US99/30066	)	
	)	Washington, D.C.
IA Filed: 17 December 1999	)	
	)	
U.S. App. No.: 09/868,501	)	September 26, 2001
	)	
National Filing Date:	)	
(Not Yet Received)	)	
	)	
For: INCREASING BRAIN GLUCOSE	)	
UTILIZATION	)	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents  
Washington, D.C. 20231

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above- identified application, and any other application relying on the filing date of the above-identified application or cross- referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

*(Check one of the boxes A-D)*

[ ] A. within three months of the filing date of the above-identified national application or within three months

of the entry into the national stage of the above-identified international application.

☒ B. before the mailing date of a first office action on the merits.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

*(Check one of the boxes "i" and "ii" below:)*

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

*(use one and delete other of following)*

☐ ii. A check (check no. \_\_\_\_\_) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) petitions under 37 CFR \$1.97(d) for consideration of this IDS. *(use one and delete other of following and this note)* A check (check no. \_\_\_\_\_) for/ Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in \$1.17(i), presently believed to be \$130 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was either

*(Check one of the boxes "a" and "b" below)*

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in \$1.56(c) more than three months prior to the filing of this IDS.

☒ 2. In accordance with 37 CFR \$1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

*(check boxes A and/or B and fill in blanks, if appropriate)*

☐ A. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with \$1.98(c), only a copy of each of the latter documents is enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

*(insert serial numbers and filing dates of prior applications)*

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document(s) \_\_\_\_\_ is (are) not in the English language. In accordance with §1.98(c), Applicant(s) states:

☐ An English translation of each document \_\_\_\_\_ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is found in the attached \_\_\_\_\_ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

*(insert concise explanation of relevance)*

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.

[ ] A concise explanation of document(s) \_\_\_\_\_  
can be found on the attached sheet.

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

[ ] 5. Other information being provided for the examiner's consideration follows:

*(insert other information)*

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	4
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**Complete if Known**

Application Number	09/868,501
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Filing Date

First Named Inventor	Daniel G. CHAIN
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### Group Art Unit

Examiner Name

Attorney Docket Number	CHAIN=4A
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## U.S. PATENT DOCUMENTS

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	3,929,813		Higuchi et al	12-30-1975	
	AB	3,962,447		Higuchi et al	06-08-1976	
	AC	4,340,603		Bodor et al	07-20-1982	
	AD	4,479,932		Bodor	10-30-1984	
	AE	4,540,564		Bodor	09-10-1985	
	AF	4,771,059		Bodor	09-13-1988	
	AG	4,888,427		Bodor	12-19-1989	
	AH	5,039,794		Wier et al	08-13-1991	
	AI	5,082,853		Bodor	01-21-1992	
	AJ	5,166,320		Wu et al	11-24-1992	
	AK	5,296,483		Bodor	03-22-1994	
	AL	5,389,623		Bodor	02-14-1995	
	AM	5,457,109		Antonucci et al	10-10-1995	
	AN	5,478,852		Olefsky et al	12-26-1995	
	AO	5,525,727		Bodor	06-11-1996	
	AP	5,556,843		Romeo et al	09-17-1996	
	AQ	5,602,133		Antonucci et al	02-11-1997	
	AR	5,624,894		Bodor	04-29-1997	
	AS	5,629,319		Luo et al	05-13-1997	
	AT	5,629,322		Guthikonda et al	05-13-1997	
	AU	5,641,796		Dominianni et al	06-24-1997	
	AV	5,646,169		Hindley et al	07-08-1997	
	AW	5,668,117		Shapiro	09-16-1997	
	AX	5,674,900		Ubillas et al	10-07-1997	
	AY	5,674,980		Frankel et al	10-07-1997	
	AZ	5,691,386		Inman et al	11-25-1997	
	BA	5,693,614		Torii et al	12-02-1997	
	BB	5,700,820		Vyas et al	12-23-1997	
	BC	5,708,012		Olefsky	01-13-1998	
	BD	5,710,153		Ohmoto et al	01-20-1998	
	BE	5,747,527		Inman et al	05-05-1998	
	BF	5,756,525		Hindley et al	06-26-1998	
	BG	5,962,004		Jannetta	10-05-1999	

Examiner  
Signature

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

(use as many sheets as necessary)

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of	4
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Application Number

09/868.501

Filing Date

**First Named Inventor**

**Daniel G. CHAIN**

### Group Art Unit

Examiner Name

Attorney Docket Number

CHAIN=4A

[illegible]

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	BI	BEGLEY et al, "Permeability of the blood-brain barrier to the immunosuppressive cyclic peptide cyclosporin A", <u>J Neurochem</u> 55(4):1222-1230 (1990)	
	BJ	BLUM-DEGEN et al, "Altered regulation of brain glucose metabolism as a cause of neurodegenerative disorders?", <u>J Neural Transm Suppl</u> 46:139-417 (1995)	
	BK	BODOR et al, "Molecular Packaging: Peptide Delivery to the Central Nervous System by Sequential Metabolism" in <u>Peptide-Based Drug Design: Controlling Transport and Metabolism</u> , Taylor et al (Eds.); Chapter 14, pp. 317-337	
	BL	BODOR et al, "Site-specific, sustained release of drugs to the brain", <u>Science</u> 214(4527):1370-1372 (1981)	
	BM	BODOR et al, "Problems of delivery of drugs to the brain", <u>Pharmacol Ther</u> 19:(3)337-386 (1982)	
	BN	BODOR et al, "A strategy for delivering peptides into the central nervous system by sequential metabolism", <u>Science</u> 257(5077):1698-1700 (1992)	

Examiner  
Signature

Date  
Considered

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STATEMENT BY APPLICANT**

(use as many sheets as necessary)

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Application Number	09/868,501
Filing Date	
First Named Inventor	Daniel G. CHAIN
Group Art Unit	
Examiner Name	
Attorney Docket Number	CHAIN=4A

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	BO	BUCKLE et al, "Non Thiazolidinedione Antihyperglycaemic Agents, 1: $\alpha$ -Heteroatom Substituted $\beta$ -Phenylpropanoic Acids", <u>Bior &amp; Med Chem Letter</u> 6(17):2121-2126 (1996)	
	BP	CANTELO et al, "[[omega-(Heterocyclamino)alkoxy]benzyl]-2,4-thiazolidinediones as potent antihyperglycemic agents", <u>J Med Chem</u> 37(23):3977-3985 (1994)	
	BQ	CLARKE et al, "Insulin binds to specific receptors and stimulates 2-deoxy-D-glucose uptake in cultured glial cells from rat brain", <u>J Biol Chem</u> 259(19):11672-11675 (1984)	
	BR	CULLINGFORD et al, "Distribution of mRNAs encoding the peroxisome proliferator-activated receptor alpha, beta, and gamma and the retinoid X receptor alpha, beta, and gamma in rat central nervous system", <u>J Neurochem</u> 70(4):1366-1375 (1998)	
	BS	DIENEL et al, "Comparison of rates of local cerebral glucose utilization determined with deoxy[1-14C]glucose and deoxy[6-14C]glucose", <u>J Neurochem</u> 59(4):1430-1436 (1992)	
	BT	DORE et al, "Distribution and levels of [125I]IGF-I, [125I]IGF-II and [125I]insulin receptor binding sites in the hippocampus of aged memory-unimpaired and -impaired rats", <u>Neuroscience</u> 80(4):1033-1040 (1997)	
	BU	DOYLE et al, "Four-day hyperinsulinemia in euglycemic conditions alters local cerebral glucose utilization in specific brain nuclei of freely moving rats", <u>Brain Res</u> 684(1):47-55 (1995)	
	BV	DUELLI et al, "Intracerebroventricular injection of streptozotocin induces discrete local changes in cerebral glucose utilization in rats", <u>Int J Dev Neurosc</u> 12(8):737-743 (1994)	
	BW	GRANNEMAN et al, "Member of the peroxisome proliferator-activated receptor family of transcription factors is differentially expressed by oligodendrocytes", <u>J Neurosci Res</u> 51(5):563-573 (1998)	
	BX	HASSELBALCH et al, "No Effect of Insulin on Glucose Blood-Brain Barrier Transport and Cerebral Metabolism in Humans", <u>Diabetes</u> 48:1915-1921 (1999)	
	BY	HOYER et al, "Brain glucose metabolism is controlled by amplification and desensitization of the neuronal insulin receptor", <u>Ann N Y Acad Sci</u> 777:374379 (1996)	
	BZ	KITAMURA et al, "Increased expression of cyclooxygenases and peroxisome proliferator-activated receptor-gamma in Alzheimer's disease brains", <u>Biochem Biophys Res Commun</u> 254(3):582-586 (1999)	

Examiner  
SignatureDate  
Considered

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Sheet 4

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Group Art Unit	
Examiner Name	
Attorney Docket Number	CHAIN=4A

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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	CA	KITAMURA et al, "Activators of peroxisome proliferator-activated receptor-gamma (PPARgamma) inhibit inducible nitric oxide synthase expression but increase heme oxygenase-1 expression in rat glial cells", <u>Neurosci Lett</u> 262(2):129-132 (1999)	
	CB	KUMAGAI, "Glucose Transport in Brain and Retina: Implications in the Management and Complications of Diabetes", <u>Diabetes metab Res Rev</u> 15(4):261-273 (1999)	
	CC	MUKHERJEE et al, "Sensitization of diabetic and obese mice to insulin by retinoid X receptor agonists", <u>Nature</u> 386(6623):407-410 (1997)	
	CD	NAKAYAMA et al, "Effect of TAK-147, a novel AChE inhibitor, on cerebral energy metabolism", <u>Neurobiol Aging</u> 17(6):849-857 (1996)	
	CE	NEUWELT et al, "Modification of the blood-brain barrier in the chemotherapy of malignant brain tumors", <u>Fed Proc</u> 43(2):214-219 (1984)	
	CF	PARDRIDGE, "Receptor-mediated peptide transport through the blood-brain barrier", <u>Endocr Rev</u> 7(3):314-330. Review (1986)	
	CG	PETROVA et al, "Cyclopentenone prostaglandins suppress activation of microglia: down-regulation of inducible nitric-oxide synthase by 15-deoxy-Delta12,14-prostaglandin J2", <u>Proc Natl Acad Sci USA</u> 96(8):4668-4673 (1999)	
	CH	POPLACK et al, "Pharmacology of Antineoplastic Agents in Cerebrospinal Fluid" in <u>Neurobiology of Cerebrospinal Fluid</u> , J.H. Wood (Ed). Plenum Press (New York, 1981), pp. 561-578	
	CI	PROKAI et al, "Chemical Delivery System to Transport a Pyroglutaryl Peptide Amide to the Central Nervous System", <u>J Am Chem Soc</u> 116:2643-2644 (1994)	
	CJ	TSUZUKI et al, "Adamantane as a brain-directed drug carrier for poorly absorbed drug: antinociceptive effects of [D-Ala2]Leu-enkephalin derivatives conjugated with the 1-adamantane moiety", <u>Biochem Pharmacol</u> 41(4):R5-8 (1991)	

Examiner Signature	Date Considered
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